

<b>Notice of Allowability</b>	Application No.	Applicant(s)
	09/974,913	THOMAS HUBSCHER
	Examiner Bao-Thuy L. Nguyen	Art Unit 1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTO-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to RCE filed on 5/12/2004.
2.  The allowed claim(s) is/are 27-32, 34, 35, 38 and 68 which have been renumbered from 1-10 respectively.
3.  The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*
  - c)  None
 of the:
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
7.  IDENTIFYING INDICIA such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
Paper No./Mail Date 7/12/04.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

Bao-Thuy L. Nguyen  
Primary Examiner  
Art Unit: 1641

**EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.
2. Authorization for this examiner's amendment was given in a telephone interview with Johnathan Grant on July 12, 2004.

The application has been amended as follows:

## CLAIMS

Claim 27 (currently amended) A lateral flow immunoassay device for detecting ~~immune reactants~~ antibodies to a specific analyte, said device comprising:

[a}] a test strip for detecting [specific antibodies] IgG, IgA and IgM in a sample, [said antibodies being specific for a specific analyte,] said test strip comprising:

- i) a sample site for applying said sample, said sample site comprising:
  - a) a sample pad to which said sample is applied; and
  - b) [a reacting substance] an IgG reacting substance present at said sample site, said substance [reacting substance having the ability to] binds to any IgG present in said sample; in an amount to allow for the complexing of said IgG,] thereby slowing down the migration of said IgG and allowing other antibodies in said sample to migrate and react at sites downstream from said sample pad prior to the migration of said IgG;
- ii) a colorimetric labeling site positioned downstream from said sample site, said colorimetric labeling site comprising [a] colorimetric labeled [analyte] binding partners for said IgG, IgA and IgM; and
- iii) at least four reaction sites positioned downstream from said colorimetric labeling site, said reaction sites comprising immobilized binding partners for said IgG, IgA, and IgM, and a control reaction site;  
wherein complexes comprising colorimetric labeled binding partner-sample antibody-immobilized binding partner are formed when said antibodies are present in said sample, and a colored line will appear at each of said reaction sites indicating the present of said complexes [wherein there is a reaction site for detecting IgG antibodies, a reaction site for

~~detecting IgA antibodies, a reaction site for detecting IgM antibodies, and a control reaction site, said reaction sites comprising anti-Ig immunoalobulin antibodies specific for specific said IgG antibodies being tested at a specific said reaction site, wherein each said reaction site binds a specific said antibody for which each said reaction site is specific, such that if said specific antibody binds with said colorimetric labeled analyte to form an Ig-colorimetric labeled analyte complex, a colored line will appear at said reaction site where said Ig-colorimetric labeled analyte complex is bound].~~

Claim 28 (currently amended) The lateral flow immunoassay device of claim [28] 27, wherein said colorimetric label is selected from the group consisting of a metal sol particle, a dyed labeled microparticle, a fluorescent labeled microparticle, and combinations thereof.

Claim 29 (previously amended) The lateral flow immunoassay device of claim 28, wherein said metal sol particle is selected from the group consisting of platinum, gold, silver, selenium, and copper.

Claim 30 (original) The lateral flow immunoassay device of claim 27, wherein said analyte is selected from the group consisting of antigens, antibodies, bacteria, viruses, protozoa, parasites, autoimmune antigens, heat shock proteins, transplantation antigens, histocompatibility antigens, and combinations thereof.

Claim 31 (original) The lateral flow immunoassay device of claim 30, wherein said analyte is selected from the group consisting of *H pylori*, *Streptococcus Group A*, *Streptococcus Group B*,

Mycobacterium tuberculosis, Mycoplasma, Chlamydiae, Rickettsiae, Herpes virus, CMV, Hepatitis A, Hepatitis C, Hepatitis B, Influenza, HIV 1, HIV 11, HTLV I & II, Chagas, Toxoplasma, transplantation antigens, Helminths, Nematodes, autoimmune antigens, heat shock proteins, histocompatibility antigens, and combinations thereof.

Claim 32 (currently amended) The lateral flow immunoassay device of claim 27, ~~[further comprising a control site] wherein said control site [containing substances that readily react with a colored solid phase] contains an immobilized substance for binding excess labeled binding partner.~~

Claim 34 (currently amended) The lateral flow immunoassay device of claim [33] 27, wherein said ~~[anti-Ig immunoglobulin antibodies]~~ immobilized binding partner are ~~[from]~~ affinity purification of immune sera selected from the group consisting of goats, rabbits, donkeys, sheep, chickens, and other animals.

Claim 35 (currently amended) The lateral flow immunoassay device of claim [33] 27, wherein said immobilized binding partners are monoclonal antibodies ~~[specific for IgM, IgA, IgE, and IgG antibodies]~~.

Claim 38 (currently amended) The lateral flow immunoassay device of claim [ ] 27, wherein said IgG reacting substances ~~[at said sample site]~~ are selected from the group consisting of protein A, protein G, lentil lectin, jacalin, concanavilin A, anti-IgG, mannan binding protein, wheat germ lectin, peanut lectin, avidcrhom, and combinations thereof.

Claim 68 (previously amended) The lateral flow immunoassay device of claim 27, wherein a complex between the IgG reacting substance and the IgG has a molecular weight greater than 1 million.

**3.** The following is an examiner's statement of reasons for allowance: the claims define over the prior art of record because the prior art of record fail to teach or make obvious a lateral flow test strip for detecting antibodies in a test sample comprising a sample contact site having an IgG reacting substance to bind and slow the migration of any IgG present in a sample, a labeled binding site site down stream from the sample contact site and at least four reaction sites downstream from the labeled site comprising immobilized capture binding substance for the sample antibodies.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

**4.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 9:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bao-Thuy L. Nguyen  
Primary Examiner  
Art Unit 1641